

Notice of Allowability

Application No.

09/444,459

Examiner

Louise N. Leary

Applicant(s)

CAMERON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Appeal Brief filed 9-8-2003.
2. ☒ The allowed claim(s) is/are 21-25,56,60-67,69-70,76,78,81-85.
3. ☒ The drawings filed on 22 November 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.


Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


LOUISE N. LEARY
PRIMARY EXAMINER

1. The following is an examiner's statement of reasons for allowance:

The reasons for allowance of the claims is that none of the prior art of record disclose or suggest (I) a method for identifying a marker that correlates with the intensity of a pain perceived by a patient comprising the steps of (i) collecting a serum sample, (ii) separating the components within the serum sample by electrophoresis in a gel, (iii) reacting the gel with diazonium salt and a substrate to form a detectable band that comprises an insoluble diazonium complex, and (iv) identifying the size and location of the detectable band to identify the marker; (II) a method of diagnosing the extent of activation of the pain sensing neurological pathway in a patient comprising (i) determining the amount of a cholinesterase pain marker in a sample from a patient, (ii) comparing the amount of cholinesterase pain marker to a threshold amount of cholinesterase pain marker, and (iii) assigning a pain status to the patient based upon the comparison; (III) a diagnostic kit for determining the level of activation of the pain sensing neurological pathway in a patient comprising at least one antibody that binds to cholinesterase in a sample; (IV) a method of diagnosing the extent of activation of the pain sensing neurological pathway in a patient comprising the steps of (i) determining the amount of a pain marker in a patient's sample, (ii) comparing the amount of the pain marker in the sample to at least one pre-determined pain marker amount, and (iii) assigning a pain status to the patient based upon the comparison, (V) a method for determining the efficacy of a treatment for pain comprising (i) determining the amount of a pain marker in a first biological sample obtained from the patient, (ii) administering the

treatment to the patient, (iii) determining the amount of a pain marker in a second biological sample obtained from the treated patient, and (iv) comparing the amount of the pain marker in the first and second biological samples; (VI) a diagnostic kit for determining the level of activation of the pain sensing neurological pathway in a patient comprising at least one antibody that binds to cholinesterase in a sample; nor (VII) a method of diagnosing the extent of activation of the pain sensing neurological pathway in a patient comprising (i) determining the amounts of at least two pain markers in a biological sample obtained from the patient, (ii) comparing the amounts of the at least two pain markers in the sample to predetermined amounts of each pain marker, and (iii) assigning a pain status to the patient based upon the comparison as claimed in the present invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

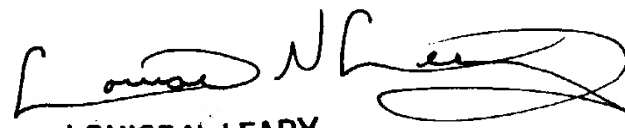
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 10 am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (517)272-0966. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

April 8, 2004